UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 C.A. No.: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO ALL CLASS ACTIONS	Judge Patti B. Saris

WATSON PHARMACEUTICALS, INC.'S RESPONSE TO CLASS PLAINTIFFS' RESPONSE TO AMGEN AND WATSON'S SUPPLEMENTAL OPPOSITION TO CLASS CERTIFICATION

As ordered by the Court in Case Management Order 32, Watson Pharmaceuticals, Inc. ("Watson") submits this memorandum in response to the "Class Plaintiffs' Response to Amgen and Watson's Supplemental Opposition to Class Certification," which was filed on August 8, 2007 (Docket No. 4609) ("Plaintiffs' Supplemental Submission").

More than six years after filing this case, Plaintiffs' submission establishes that they have still not found a single class representative for Watson adequate to represent any of the classes that they have asked this Court to certify. In their most recent filing, Plaintiffs claim appropriate reimbursements for only one proposed class representative, Sheet Metal Workers National Fund ("Sheet Metal Workers"), for Class 2. But Watson has already established that the reimbursement Plaintiffs claim for Sheet Metal Workers for the one multi-source drug they mention could not have been for Watson's drug. Furthermore, the reimbursements claimed for Ferrlecit® (a single-source drug) by Sheet Metal Workers do not establish an adequate class representative, since the

reimbursements occurred after the period for which the Court could certify a class (if at all). Therefore, the Court should deny class certification as to Watson.

Background

In its Order dated August 16, 2005, relating to class certification for Track One, the Court held, correctly, that "[p]laintiffs must establish that there is an individual class representative with standing to sue each defendant." *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 80 (D. Mass. 2005). The Court also ruled that, to establish standing, Plaintiffs must "disclose the documents demonstrating that the proposed class representatives made co-insurance payments (at least in part) under Medicare Part B based on AWP." *Id.* at 81.

After the parties filed opposing pleadings on whether Plaintiffs needed to do so, Plaintiffs filed, on May 8, 2006, a Motion, a supporting Memorandum, and a proposed Order seeking certification of class representatives as to the Track Two Defendants. In relevant part (because Plaintiffs have now conceded they have no Class 1 representative for Watson), these papers sought certification of Sheet Metal Workers for a Massachusetts-only Class 2, and Pipefitters Local 537 Trust Funds ("Pipefitters") for a Massachusetts-only Class 3. Watson (among other defendants) filed an individual response on June 15, 2006. Watson's response went, drug by drug, through the reimbursements for Sheet Metal Workers and Pipefitters to show that the generic multi-source drug reimbursements claimed to establish standing for class representatives as to Watson were not Watson's drugs. Watson Pharmaceuticals, Inc.'s Individual Memorandum in Opposition to Class Certification, filed June 15, 2006 (redacted version

filed June 30, 2006) (Docket No. 2810) ("Watson's Opposition") at 5-6. Watson reviewed not only the materials submitted to the Court, but also the discovery materials on claims data provided by Sheet Metal Workers and Pipefitters, and found that any administrations of the generic multi-source drugs claimed for Watson occurred during time periods when Watson had little, if any, market share as to those drugs.[1] *Id.* Therefore, it was nearly impossible that any of the multi-source drugs administered to these patients had been distributed by Watson. *Id.* at 6. Indeed, Plaintiffs acknowledged that Watson had addressed discovery materials, rather than just the materials that had been attached to their Motion. Plaintiff's Reply Memorandum in Support of Motion to Certify Claims with Respect to Track 2 Defendants, filed July 19, 2006 (Docket No. 2889) at 42 ("Watson is the sole Track 2 Defendant who examined Sheet Metals' entire Massachusetts production rather than the sample" submitted to the Court).

On August 8, 2007, Plaintiffs filed a submission that claimed that Sheet Metal Workers does have coverage for Ferrlecit in multiple states (other than Massachusetts) and coverage in 2003 for a multi-source drug (described as "Dexamethasone Sodium" in the pleading, but, presumably, referring to dexamethasone sodium phosphate). Plaintiffs' Supplemental Submission at 5. Plaintiffs attached a claim form that showed a reimbursement of only 8 cents for a Sheet Metal Workers beneficiary for dexamethasone

[1] Watson did not review the claims forms for administrations of lorazepam or fluphenazine. Neither drug is a subject drug for Watson: (1) lorazepam because the injectable product was a new drug stricken from the case by the Court's April 13, 2006, Order and (2) fluphenazine because Watson never marketed an injectable version of this drug.

sodium phosphate administered on September 10, 2003. Declaration of Steve W. Berman, Ex. 5, Plaintiffs' Supplemental Submission, filed August 8, 2007 (Docket No. 4610). Apparently forgetting their earlier concession that Watson had, indeed, reviewed all Massachusetts reimbursements produced in discovery (rather than just the claims cited in prior pleadings), Plaintiffs inaccurately stated that Watson claimed there were no reimbursements relating to its drugs based on an analysis of "*sample* Massachusetts-only Sheet Metal Claims data that was attached to the Affidavit of Glenn Randle." Plaintiffs' Supplemental Submission at 5. However, all of the reimbursements claimed – then and now – for Sheet Metal Workers and Pipefitters for generic multi-source drugs occurred well after Watson discontinued marketing those drugs, and during periods when IMS Health, Inc. ("IMS") data showed there were either no Watson multi-source subject drugs on the market, or such a small percentage as to rule out any reasonable possibility that the reimbursements related to a Watson drug.

At the hearing on August 27, 2007, the Court indicated that it will likely permit Plaintiffs to proceed to an early trial against Watson on its single-source subject drug, Ferrlecit, although it indicated that the matter was under advisement. Ferrlecit is an injectable iron supplement (sodium ferric gluconate) which is indicated for treatment of iron-deficiency anemia in patients undergoing dialysis for End-Stage Renal Disease ("ESRD"). Declaration of Timothy Callahan ("Callahan Decl.") ¶ 4, attached as Ex. 1. Almost all dialysis patients who received Ferrlecit from its introduction in the fourth quarter of 1999, through December 2003 (the end of the class period, under the Court's earlier rulings) were covered by Medicaid or Medicare, since ESRD patients are not

required to be elderly to qualify for Medicare. *See* 42 U.S.C. § 426-1; Medicare Dialysis Facilities: Beneficiary Access Stable and Problems in Payment System Being Addressed, GAO-04-450 (June 2004) at 5, attached as Ex. 2 ("Individuals with ESRD are eligible for Medicare benefits regardless of their age. In 2001, Medicare covered about 90 percent of the 406,000 individuals with the disease."). Watson internal projections also show that a large percentage of dialysis patients receiving Ferrlecit are on Medicare. Indeed, they show that in 2001 about 75 percent of Ferrlecit patients were covered by Medicare, 15 percent by Medicaid, and only about 10 percent by private insurance. Callahan Decl. ¶ 6.

At the recent hearing, the Court also stated that Plaintiffs' claims relating to multi-source drugs are "a mess." Transcript of August 27, 2007 hearing, at 24 ("almost intractable causation issue"), 31 ("Multi-source is a mess, okay?"), 32 ("a very difficult causation issue"). The Court deferred consideration of class certification on multi-source drugs until after the trial for Amgen, Aventis, and Watson for Ferrlecit. The Court indicated that it has apparently decided to treat Plaintiffs' submissions as a Motion for nationwide classes (though Plaintiffs have not moved for Nationwide Class Certification, or submitted a proposed Order, so it is difficult to determine what Plaintiffs seek). *Id.* at 43 ("If I do a national class . . . .").

Following the hearing, Watson's counsel requested that Plaintiffs provide evidence of the reimbursements claimed for Ferrlecit. On August 13, 2007, Plaintiffs provided a chart with citations to Sheet Metal Workers claim forms for reimbursements for Ferrlecit (none of them in Massachusetts, and therefore not discussed in Watson's earlier opposition to class certification). Declaration of Michelle L. Butler ("Butler

Decl.") ¶¶ 2, 5 & Ex. A, attached as Ex. 3.[2] Curiously, although Plaintiffs have only sought certification as to Sheet Metal Workers and Pipefitters, the chart also included claimed reimbursements for drugs by United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund ("UFCW") for Classes 2 and 3 and Pirelli Armstrong Tire Corporation Retiree Medical Benefits Trust ("Pirelli") for Class 3. *Id.* Watson has carefully reviewed the claims data and determined that all reimbursements for Ferrlecit, whether from Sheet Metal Workers or from Pirelli, occurred within the period from August 2001 to December 2003.[3] *Id.* ¶ 5. Accordingly, for reasons set forth below, the proposed class representatives as to Ferrlecit do not have standing or adequacy to represent the proposed classes, based on the citations provided.

The chart provided by Plaintiffs also included citations to alleged reimbursements by Sheet Metal Workers, Pirelli, and UFCW for multi-source drugs.[4] Again, without Plaintiffs' having moved to certify UFCW or Pirelli as class representatives for Watson,

---

[2] In response to Watson's request for information related to certain of the claimed reimbursements, Plaintiffs sent a revised chart on September 7, 2007, which dropped several references to alleged reimbursements. *Id.* ¶ 3 & Ex. B.

[3] There were no administrations of Ferrlecit in the Pipefitters data, and Plaintiffs' September 7, 2007, chart showed no claim of UFCW reimbursement for Ferrlecit.

[4] Plaintiffs have characterized INFeD® as a multi-source drug, presumably because it shared a J-Code with a competitive product. There are no products that have been rated by the Food and Drug Administration as therapeutically equivalent to INFeD. Nor is it a generic drug. Nevertheless, in its review of the documentation produced by Plaintiffs, Watson has found no reimbursements by Sheet Metal Workers or Pipefitters for administrations of INFeD prior to December 2000. Later administrations of the drug are subject to the same analysis as Ferrlecit, leading to no adequacy or standing for Sheet Metal Workers or Pipefitters as to INFeD, either.

the chart includes data for those two entities.[5] Watson's attorneys have carefully reviewed the claims data cited by Plaintiffs and determined that all reimbursements for the generic multi-source drugs by Sheet Metal Workers occurred for administrations within the period from June 2000 through November 2003, and therefore it was highly unlikely – if not impossible – that the drugs were Watson's drugs. Butler Decl. ¶ 8. Moreover, as discussed in Watson's Opposition, all reimbursement for the generic multi-source drugs by Pipefitters occurred for administrations within the period from August 1999 to February 2004, and therefore it was also highly unlikely or impossible that the drugs were Watson's drugs.

Argument

I. Plaintiffs Have Not Proposed a Class Representative with Standing, Adequacy or Typicality Relating to Watson and its Subject Drugs.

Plaintiffs must show by a preponderance of the evidence that proposed class representatives have standing. *Lee v. City of Chicago,* 330 F.3d 456, 468 (7th Cir. 2003); *Prado – Steiman v. Bush,* 221 F.3d 1266, 1279-80 (11th Cir. 2000). In fact, Watson can show by more than a preponderance of the evidence that the proposed class representatives do not have standing.

In the massive amount of claims data provided in discovery and in the portions of that data cited in Plaintiffs' pleadings, Plaintiffs have not produced adequate evidence of any reimbursements by Sheet Metal Workers or Pipefitters for the generic multi-source

[5] Six days ago, Plaintiffs sent Watson's attorneys claims information from UFCW. Butler Decl. ¶ 9.

drugs alleged to be subject drugs as to Watson. Even if appropriate reimbursements for Watson's multi-source drugs had been established, they do not provide a basis for certifying a Watson class for single-source drug Ferrlecit: consideration of class certification as to multi-source drugs has been deliberately postponed.

Furthermore, the reimbursements by Sheet Metal Workers for Ferrlecit do not establish standing, adequacy, or typicality, because all of those reimbursements occurred after December 2000. For reasons detailed below, even if a class period should be certified as to Ferrlecit, the class period for dialysis drugs like Ferrlecit should end in December 2000, at the latest, when Congress – knowledgeable about the size of the "spread" – took deliberate action to ensure that dialysis clinics' profits on Medicare drug reimbursements cross-subsidized the losses on Medicare reimbursements for dialysis treatments. Unlike oncology clinics discussed in the Court's June 21, 2007, decision, Watson can establish that the amount of cross-subsidization was appropriate when Congress took action in 2000 to protect the "spread." Any liability for Medicare reimbursements should be closed as of December 2000. Since Sheet Metal Workers has no reimbursement for Ferrlecit prior to December 2000, it would be an inadequate representative for Class 2.

Finally, the Court should not certify UFCW or Pirelli as class representatives for Watson, since Plaintiffs have not moved to certify them; since UFCW has no claims for reimbursement of Ferrlecit prior to June 2004; and since Pirelli, like Sheet Metal Workers, has no claims of reimbursement for Ferrlecit prior to 2001.

A. Plaintiffs Cannot Rely on Multi-source Drug Reimbursements to Support Class Certification as to Ferrlecit; Even if They Could, None of the Drugs Reimbursed Was Watson's.

In their August 8, 2007, pleading, Plaintiffs claim only that they can support Sheet Metal Workers as a Class 2 representative for Watson's drugs, and then based only on reimbursements for Ferrlecit and a multi-source drug, dexamethasone sodium phosphate.

Plaintiffs are not seeking certification of class representatives as to multi-source drugs at this time, and it would be monumentally inappropriate for the Court to consider the reimbursement for a multi-source drug as an adequate basis for a class representative to be certified for Watson's single-source drug. As the Court has correctly characterized multi-source drugs, in light of its prior rulings, multi-source drugs are "a mess," and liability might never be established as to any of those drugs, especially as to Watson. It would be improper for the Court to certify a class based on a class representative's activities that will almost definitely result in judgment for the defense. A class representative is not adequate if its only connection to the underlying activities relates to a portion of the case that will probably be rejected by the Court. *See Great Rivers Coop. v. Farmland Indus., Inc.*, 120 F.3d 893, 899 (8th Cir. 1997) (class certification denied because named plaintiff time barred); *Weinberger v. Retail Credit Co.*, 498 F.2d 552, 556 (4th Cir. 1974) (same); *Sperling v. Donovan*, 104 F.R.D. 4, 9 (D.D.C 1984) (named representatives' claims atypical because time-barred). *See also Commander Properties Corp. v. Beech Aircraft Corp.*, 164 F.R.D. 529, 527-42 (D. Kan. 1995) (denying motion for class certification after noting greater flexibility when class representatives' claims are narrower in time than claims of the class).

It was for that reason that the Court, at the August 27, 2007, hearing, correctly rejected the proposed Class 1 representative for Amgen, since the Class 1 representative could only show administration of the Amgen drug in 2004, after the close of the class period found by the Court. Transcript of August 27, 2007 hearing, at 21-22. Likewise, the Court should reject certifying a class as to Ferrlecit based on reimbursements for multi-source drugs, since multi-source drugs present their own conundrum.

Moreover, Watson has established in its prior filings that it is nearly impossible that the dexamethasone sodium phosphate reimbursed in 2003 (a de minimus reimbursement, at that) was manufactured or distributed by Watson. As set forth in Watson's Opposition and supporting Declarations, IMS data were reviewed for all relevant periods, and it was demonstrated that Watson and its affiliates were responsible for none or for a very small percentage of sales of the particular drugs involved. *See* Declaration of Jeffrey L. Johnson ("Johnson Decl.") ¶¶ 18-27, attached as Ex. 1 to Watson's Opposition. Watson established that it and its affiliate did not manufacture the drug after late 1998, and that the dexamethasone sodium phosphate administered in September 2003 could not have been Watson's based on the fact that the product had not been manufactured by Watson for five years and on the applicable IMS data. Johnson Decl. ¶¶ 16, 26 (showing 1,000 extended units – the smallest unit recorded by IMS – attributed to Watson compared to 36,897,000 for the four largest distributors).

Therefore, the Court must deny class certification for Ferrlecit for Watson based on any reimbursements for multi-source products. Even if the Court decides to consider certifying a class as to Watson for Ferrlecit based on any multi-source drugs, Watson's

class certification decision and trial should be postponed to the time when other Track Two multi-source issues will be considered by the Court.

B. Reimbursements for Ferrlecit After December 2000 Do Not Provide an Adequate Basis for Certification of a Class 2 or 3 Representative.

A plaintiff's motion for class certification should be denied when proposed class representatives are subject to defenses that are unique to them and thus the proposed class representatives fail to meet the typicality requirement of Fed. R. Civ. P. 23(a)(3) and the adequacy requirement of Fed. R. Civ. P. 23(a)(4). As this Court recently noted:

> Courts have held that
>
> to defeat class certification, a defendant must show some degree of likelihood that a unique defense will play a significant role at trial. Therefore, typicality is defeated when the proposed class representative is subject to a unique defense that has the likelihood of becoming the main focus of the litigation thereby distracting attention from the issues common to the class.

In re Neurontin Mktg. and Sale Practices Litig., ---- F. Supp.2d ----, 2007 U.S. Dist. Lexis 63898, at *54 (D. Mass. Aug. 29, 2007) (quoting *Bayshore Ford Truck Sales, Inc. v. Ford Motor Co.*, 2006 U.S. Dist. LEXIS 64264, at *39 (D.N.J. 2006) (internal quotation marks and alterations omitted)).

i. A June 2000 OIG Report on ESRD Drugs and Congressional Enactment of BIPA in December 2000 Bar Class Certification Based on Reimbursements for Ferrlecit After December 2000.

Watson can plainly show that Plaintiffs' proposed class representatives will be subject to a unique additional defense that Watson intends to make a main focus of the litigation. Plaintiffs have only identified class representatives with claims for Ferrlecit well after December 2000. But the class period for Ferrlecit must end in December 2000.

In June 2000, the Office of the Inspector General ("OIG") of the Department of Health and Human Services ("HHS") issued Report OEI-03-00-00020, Medicare Reimbursement of End Stage Renal Disease Drugs. A copy is attached as Ex. 4. This report, specific to ESRD drugs, compared Medicare reimbursement for dialysis drugs (95 percent of AWP) to the acquisition costs for the Department of Veterans Affairs ("VA"). The report specifically discussed iron dextran, which, like Ferrlecit, is an injectable iron supplement used to treat ESRD patients undergoing hemodialysis. The report showed that Medicare could save 45.85 percent on iron dextran by using VA acquisition costs. The projected savings for the five ESRD drugs reviewed if Medicare reimbursement was cut to VA acquisition cost ranged from a low of 36.9 percent to a high of 55.9 percent. When computed to show the "spread," the percentages were 58.4 percent to 126.8 percent. The spread for iron dextran was 84.5 percent.[6] The spread reflected by the OIG report for iron dextran approximated the actual spread on INFeD (Watson's iron dextran) and was greater than that for Ferrlecit. These were, at the time, about 74 to 103 percent and 44 to 74 percent, respectively. Callahan Decl. ¶ 8. Spreads on INFeD and Ferrlecit stayed within the range of ESRD drug spreads reflected in the OIG report through the end of 2003. *Id.* ¶ 9.

---

[6] The percent spread was calculated by taking the Medicare allowed amount for iron dextran, $35.82, and subtracting the VA acquisition cost for iron dextran, $19.41. That difference, $16.41, was then divided by the VA acquisition cost of $19.41 to obtain the 84.5 percent spread).

The OIG recommended that the Health Care Financing Administration ("HCFA"), predecessor of the Centers for Medicare & Medicaid Services ("CMS"), reduce reimbursement for ESRD drugs, and HCFA concurred. HCFA expressed an intention to "review payment rates for . . . administration to ensure they are adequate as we reduce payments for the drugs themselves to the prices that physicians pay."[7] Medicare pays dialysis clinics a composite rate, which covers dialysis treatments and required supplies and routine drugs. *See* 42 U.S.C. § 1395rr; 42 C.F.R. Part 413, Subpart H. Medicare also pays dialysis clinics a separate reimbursement for "separately billed drugs," like iron dextran and Ferrlecit. 42 U.S.C. § 1395rr(b)(13). HCFA thus acknowledged in its response to the OIG report that dialysis treatment rates would have to be raised when the cross-subsidization for separately billable drugs was cut.

In December 2000, just six months after the OIG report on ESRD drugs, Congress enacted the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No. 106-554, 114 Stat. 2763 (2000) ("BIPA 2000"). BIPA 2000 instituted a moratorium on change in Medicare drug reimbursement pending a Government Accounting Office ("GAO") report, which this Court has already discussed. *See In re Pharm. Indus. Average Wholesale Price Litig.,* 491 F. Supp. 2d 20, 43-44 (D. Mass. 2007). More importantly for the Court as it considers class certification as to Ferrlecit, Congress also enacted, in a separate section of BIPA 2000, provisions specific to the

---

[7] *See* Ex. 4 at 22. In a seeming editing error, HCFA's comment to the OIG report on ESRD Drugs referenced "chemotherapy administration" notwithstanding the fact that the report focused on ESRD drugs, and therefore, dialysis treatments. *Id*.

renal dialysis composite rate. BIPA 2000, § 422. Subsection (c) of that section required the Secretary of HHS to "develop a system which includes, to the maximum extent feasible, in the composite rate used for payment . . . payment for clinical diagnostic laboratory tests and drugs . . . that are routinely used in furnishing dialysis services to [M]edicare beneficiaries but which are currently separately billable by renal dialysis facilities." BIPA 2000, § 422(c)(1) (emphasis added). Significantly, Congress also required the GAO to study access to dialysis services in subsection (d), including "whether [M]edicare payment levels are appropriate, taking into account audited costs of facilities for all services furnished. . . ." BIPA 2000, § 422(d)(1). The upshot of section 422(c) (requiring HCFA to look at updating the composite rate) and 422(d) (requiring a GAO study of access to services, including whether Medicare reimbursement was adequate) along with section 429 (imposing a moratorium on a reduction in Medicare drug reimbursement) evinces clear Congressional intent to stabilize ESRD drug reimbursement rates, even when Congress knew the AWP on iron dextran was nearly 90 percent above acquisition costs.

With regard to ESRD drugs, then, Congress's action in enacting BIPA 2000 was the equivalent of Congress's action, with regard to other Part B drugs, in enacting the Medicare Modernization Act ("MMA") in 2003. Pub. L. No. 108-173, § 623, 117 Stat. 2006 (2003), codified at 42 U.S.C. § 1395rr. It was Congress's action in the MMA that led the Court to conclude that the period for liability with regard to Medicare Part B drugs closed in 2003. Similarly, in enacting BIPA 2000, Congress was aware specifically of spreads for ESRD drugs, and mandated that rates not be reduced unless and until

Medicare instituted appropriate, countervailing increases in Medicare's dialysis treatment reimbursement. Thus, consistent with the Court's prior ruling, any period for liability for ESRD drugs with spreads in the same range as those in the OIG report (including iron dextran and Ferrlecit) ended in December 2000. Class representatives claiming adequacy and typicality for reimbursements after that point must fail.

The findings of the OIG report relating to iron dextran apply to Ferrlecit, the drug for which Plaintiffs now seek class certification. The spreads on the two drugs were in the same range, and were both within the range of spreads for ESRD drugs included in the OIG report. Callahan Decl. ¶ 8. Ferrlecit was doubtless not mentioned in the OIG report because it was new to the market, *id.* ¶ 4, and the OIG report relied on data from 1999. But, because the spreads were within the range cited in the report, Congress's knowledgeable mandate that the rates not be changed also applies to Ferrlecit.

Therefore, claims based upon reimbursement for Ferrlecit after December 2000 are barred, and class certification based on these reimbursements should not be granted.

ii. The 2005 Decrease in Medicare ESRD Drug Reimbursement and Increase in Treatment Reimbursement Confirmed that the ESRD Drug Spread Appropriately Cross-subsidized Dialysis Clinics for Inadequate Treatment Reimbursement Rates.

In its June 21, 2007, ruling, the Court rejected arguments relating to cross-subsidization in oncology clinics because the Court found no evidence that the amount of cross-subsidization created by spreads was equivalent to losses caused by inadequate Medicare reimbursement for administration of the drugs. *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 37-38 ("no evidence about the extent of a

shortfall in the costs of administration;" "no evidence that any margin over the 20 to 25 percent industry-wide formula was needed to compensate doctors"). However, with regard to ESRD drugs like Ferrlecit, Watson can easily make such a showing.

Importantly, the government's decision to maintain Medicare reimbursement for ESRD drugs in 2000 is not properly attributable to legislative or administrative lag. Rather, Congressional testimony and the MMA indicate that Congress, HCFA, and others knew that ESRD drug reimbursements were cross-subsidizing dialysis clinics in an amount appropriate to cover the inadequate composite rate.

The ESRD provisions of the MMA make it clear that ESRD cross-subsidization was necessary. These sections mandated that for 2005, 2006, and, 2007, the aggregate amount spent by the Medicare program on dialysis must be the same as if the provision had not been enacted. 42 U.S.C. § 1395rr(b)(12)(E)(i-ii). *See also* CMS End Stage Renal Disease Composite Rate Fact Sheet (Apr. 2006), attached as Ex. 5 ("A key purpose of § 623 of the MMA is to eliminate the cross-subsidization of composite rate payments by drug payments. . . . Medicare will spend the same amount of money as would have been spent under the prior system, but the cross-subsidy will be eliminated.").

Congress's action in the MMA in 2003 is entirely consistent with CMS's views as expressed by then CMS Administrator Thomas Scully in Congressional testimony. In a hearing before the Health Subcommittee of the House Ways and Means Committee on October 3, 2002, Mr. Scully repeatedly indicated that CMS had been aware of the cross-subsidization issue for some time, and considered it a necessary element of adequate reimbursement to, among others, dialysis clinics. Mr. Scully first noted that dialysis

clinics were one group "where providers rely on the cross-subsidy from higher average wholesale prices for drugs to make up for what they perceive, in some cases probably correctly, to be an underpayment for their basic services."[8] Mr. Scully then confirmed the need for cross-subsidization, "[W]e do think that we need to find the right amount for practice expenses. As we reduce the overpayments for AWP, that we need to make adjustments . . . for dialysis facilities." *Id.* Mr. Scully again stated "I think it is clearly appropriate to put the practice expense funds back where they are needed . . . areas we have identified that rely on AWP for margins are . . . dialysis facilities." *Id.* at 7; *see also id.* at 12 (dialysis centers "rely on margins from AWP").

Mr. Scully, when he testified at his deposition in this case, repeated that the cross-subsidization for ESRD drugs prior to MMA had been appropriate, and that the cross-subsidization resulted in a one-for-one dollar match for dialysis clinics when rates were adjusted after MMA, so that dialysis clinics maintained the same revenue. Excerpts from May 15, 2007 deposition of Thomas M. Scully, attached as Ex. 7, at 125, 127-128 ("Congress very consciously, because dialysis [clinics] really did have bad margins, Congress instructed the agency from AWP savings on dialysis dollar for dollar that came out went back into a drug add-on [for fees for services]. Dollar for dollar, there are no savings."), 348-49 ("I did know on the dialysis side, it probably was appropriate to put all of it [savings by reducing drug reimbursements] back in [to increased fees for services]").

---

[8] Medicare Payments for Currently Covered Prescription Drugs: Hearing Before the Subcomm. on Health of the H. Comm. on Ways and Means, 107th Cong. 10 (2002) (statement of the Hon. Thomas A. Scully, Administrator, Centers for Medicare & Medicaid Services), attached as Ex. 6.

Significantly, all reimbursements claimed for Sheet Metal Workers for Ferrlecit appear to have occurred at dialysis clinics or outpatient facilities. Butler Decl. ¶ 6.

In other words, the cross-subsidization for ESRD drugs like Ferrlecit was appropriate to offset losses to dialysis clinics from insufficient dialysis administration fees. Congress knew it, and supported it, in December 2000 when BIPA was enacted. And the evidence has shown that, if the spread on Ferrlecit had been eliminated or dropped to 20-25 percent above acquisition costs, Congress and HCFA would have acted to ensure that basically the same amount of Medicare money went to dialysis clinics. More specifically, Medicare patients (to the extent they did have a copayment) and third party payors would have ended up paying 20 percent of the same amount, just apportioned differently between drug costs and administration costs.

Therefore, the Court should not certify a class as to Ferrlecit based on reimbursements after December 2000.

C. The Court Should Not Certify Classes for Pirelli or UFCW.

As stated above, Plaintiffs have not moved for Pirelli or UFCW to be certified as class representatives, and have not submitted a proposed order certifying them. However, since Plaintiffs sent Watson's counsel material claiming reimbursements for these entities, Watson feels compelled to point out the serious error that the Court would commit in certifying either entity as a class representative, at this point.

Due to the fact that Plaintiffs have never moved to certify these entities as nationwide class representatives for Track Two, Defendants have conducted only very limited discovery as to these entities. Plaintiffs' attorneys by subterfuge (not having

moved for these entities to be class representatives and by most recently designating relevant records less than a week ago) have foreclosed the possibility of appropriate discovery. If Plaintiffs now seek to certify classes as to Pirelli and UFCW, they have blind-sided Defendants in a most reprehensible way.

Moreover, this Court has repeatedly stated that it wishes to contract, not expand, this case. Transcript of August 27, 2007 hearing, at 8 ("I'm not here expanding at this point. I want to contract."). This effort is reflected in the Court's categorical rejection of Plaintiffs' repeated attempts to add new drugs to the case. April 10, 2006, Electronic Order (Document entry after No. 2407) ("I strike the new drugs."). To permit Plaintiffs to now expand their motion for class certification six years after the case was filed, and more than a year after their motion for class certification was filed, would be inefficient, unfair, and a denial of due process. Moreover, if, indeed, Plaintiffs are seeking to certify Pirelli and UFCW as class representatives for Track Two, Defendants must be granted adequate time to take discovery, to analyze claimed reimbursements, and to file pleadings opposing such a motion, if one is allowed.

Plaintiffs cannot rely on the filing of the Fifth Amended Complaint to support class certification of Pirelli and UFCW. Pirelli and UFCW were also included as Plaintiffs in the Third Amended Complaint, filed in October 2005, well before Plaintiffs filed their Motion for Class Certification as to Track Two Defendants, and they did not seek to have the two certified as class representatives in their prior motion. Their inclusion in the Fifth Amended Complaint did nothing to alert the Track Two Defendants that they needed to secure discovery as to Pirelli and UFCW. Indeed, the Track Two

defendants did not have an inkling that they would need to analyze the massive amounts of nationwide data for any proposed Class 2 or Class 3 proposed representatives until less than a month ago (at the August 27 hearing), and still cannot be tasked with this responsibility as to Pirelli and UFCW now, since Plaintiffs still have not moved for their certification as class representatives.

Therefore, the Court cannot certify Pirelli or UFCW as class representatives for any Track Two Defendants.

Conclusion

For the reasons stated herein, the Court should deny class certification as to Watson.

Respectfully submitted,

/s/ Douglas B. Farquhar
Douglas B. Farquhar
Michelle L. Butler
James P. Ellison
Hyman, Phelps & McNamara, P.C.
700 13th Street, N.W., Suite 1200
Washington, D.C. 20005
(202) 737-5600
(202) 737-9329 (Fax)

Date: September 14, 2007

CERTIFICATE OF SERVICE

I hereby certify that I, Douglas B. Farquhar, caused a true and correct copy of the foregoing **WATSON PHARMACEUTICALS, INC.'S RESPONSE TO CLASS PLAINTIFFS' RESPONSE TO AMGEN AND WATSON'S SUPPLEMENTAL OPPOSITION TO CLASS CERTIFICATION** and exhibits to be delivered on September 14, 2007, to all counsel of record by electronic service, a copy to LexisNexis File and Serve for posting and notification to all parties.

By: /s/ Douglas B. Farquhar

Douglas B. Farquhar
Hyman, Phelps & McNamara, P.C.
700 13th Street, N.W., Suite 1200
Washington, D.C. 20005
(202) 737-5600
(202) 737-9329 (Fax)